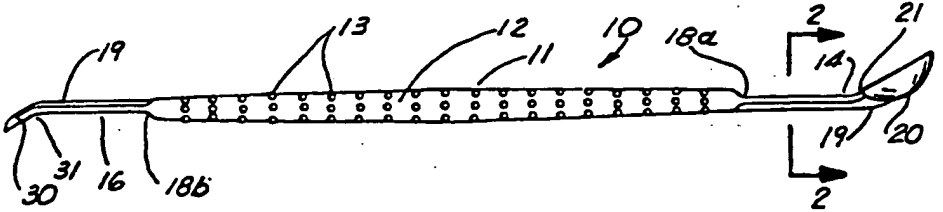


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<p>(21) International Application Number: PCT/US94/03531 (22) International Filing Date: 29 March 1994 (29.03.94) (30) Priority Data: 08/038,113 29 March 1993 (29.03.93) US (71) Applicant: SMITH & NEPHEW RICHARDS, INC. [US/US]: 1450 Brooks Road, Memphis, TN 38116 (US). (72) Inventors: LYONS, Chris; 6379 Arbor Creek Trail, #205, Memphis, TN 38115 (US). ROCCO, Richard, A.; 936 Ten Oaks Drive, Collierville, TN 38017 (US). (74) Agents: KRIEGER, Paul, E. et al.; Pravel, Hewitt, Kimball & Krieger, 1177 West Loop South, 10th floor, Houston, TX 77027-9095 (US).</p>		<p>(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published With international search report.</p>
<p>(54) Title: SURGICAL INSTRUMENTS</p> <p>(57) Abstract</p> <p>A surgical instrument (10) for use in orthopedic reconstructive joint procedures to remove uncured bone cement, including an elongated handle (12) and opposing ends (14, 16). The handle (12) has a symmetrical midline (11) and tapered portions extending toward the opposing ends (14, 16), the handle (12) having raised dimples (13) to facilitate gripping. Each opposing end (14, 16) includes a sculpting tool (20, 30) disposed at a reverse angle relative to the opposite sculpting tool and having a shaped configuration for sculpting uncured bone cement. The handle (12) further includes an integral reinforcing ridge (19) between the handle (12) and the sculpting tool (20, 30).</p> 		

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TITLE: SURGICAL INSTRUMENTS

SPECIFICATION

Field of the Invention

The present invention relates to surgical instruments for use in orthopedic implant procedures and, more particularly, to cement sculps useful in removing excess uncured bone cement after a prosthesis has been implanted.

Background of the Invention

Although prosthetic human body implants can be anchored in bone through a variety of different techniques such as, for example, friction fit, threads, tissue ingrowth surfaces and bone cements, the most popular technique is still the use of bone cement. A typical bone cement is polymethylmethacrylate (PMMA) in the form of a putty-like substance that can be kneaded and shaped for insertion into a cavity prior to placement of the implant.

During orthopedic surgery the portion of a bone in which an implant is to be inserted, is exposed and an opening or cavity is reamed in the bone. A quantity of bone cement is prepared in a known way and inserted into the cavity. After the prosthesis is properly placed, the cement cures and firmly anchors the prosthesis in place.

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During placement of the prosthesis, excess uncured cement tends to extrude from the cavity. This cement is relatively heavy and tends to thicken as it cures. Thus, any instrument that is used to
5 remove or sculpt the cement needs to be relatively strong, but at the same time needs to have a relatively small profile so as to allow the removal of excess cement from difficult-to-reach areas without obstructing the surgeon's vision.

10 Metal bone curettes are commonly used to remove the excess bone cement. However, since alloys utilized in many prosthetic replacement devices are susceptible to scratches and notches from metal instruments, metal is not satisfactory. Even a
15 slight scratch in the implant could make it susceptible to corrosion, resulting in implant failure. If the scratch or notch is deep enough and in a critical location, such as in the neck of a hip prosthesis where there are high stress
20 concentrations, the implant could be weakened.

While attempts have been made to develop a reusable curette or sculpting instrument formed of plastic, these instruments proved less than
25 satisfactory because they were too bulky, difficult to grasp, and had a tendency to break during use. These instruments were designed with a shape similar to the metal curettes where a separate instrument incorporated only one shaped end (i.e. large spoon, small spoon, knife and loop) which required the
30 surgeon to change instruments when he or she found it necessary to use more than one curette.

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Summary of the Invention

According to a first aspect of the present invention there is provided a disposable surgical instrument for use in removing uncured bone cement, comprising:

- a) an elongated handle and opposing end sections;
- b) the handle including a middle portion and tapered portions extending toward the opposing end sections, the handle including external gripping means;
- c) each opposing end section including a sculpting means having a shaped configuration for sculpting uncured bone cement;
- d) the end sections including an integral structure reinforcing means extending between the handle and the sculpting means; and
- e) the handle and opposing end sections being formed as a unitary structure of a sterilizable molded plastic.

By incorporating sculpting means on each end of the surgical instrument the need to change instruments when excess cement is being removed from the implant site can be minimised. For example, an instrument may have a first tool in the shape of a large spoon on one end for the removal of large quantities of uncured cement and a second tool in the shape of a small spoon on the other end for the removal of smaller quantities of uncured cement in more confining spaces (such as the posterior aspect of the tibia for a knee prosthesis). A second

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instrument may have a first tool in the shape of a knife or blade for cutting uncured cement away from the periphery of the implant/bone interface on one end and a second tool in the shape of a loop on the opposite end for the removal of uncured cement in the narrow spaces of an intramedullary canal.

The sculps are preferably formed of a strong, sterilizable plastic such as for example, cellulose acetate propionate, which may be discarded after use. The invention can eliminate the problem of implant scratching and notching, common with metal instruments, and can provide light weight, specifically designed instruments for the removal of excess uncured cement during orthopedic implant procedures.

According to a second aspect of the present invention there is provided a surgical instrument for removing uncured bone cement, comprising:

- a) an elongated handle formed of a sterilizable plastic material having first and second opposing ends;
- b) the handle including a symmetrical midline and tapered portions extending from the midline, the handle including raised dimples arranged in a pattern along its exterior;
- c) the first opposing end including a loop having an opening in the center for the removal of uncured cement in narrow spaces of a cavity and having sides of a thickness sufficient to remove uncured cement without bending;

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d) the second opposing end including a knife generally in the shape of an oval and tapering to a point for removing uncured cement between a bone and a prosthesis, the blade being contiguous with the handle and disposed at a reverse-angle relative to the first opposing end; and

e) the handle further including an integral raised ridge placed between the handle and the loop and blade.

According to a third aspect of the present invention there is provided a surgical instrument for removing uncured bone cement, comprising:

a) an elongated handle formed of a sterilizable plastic material having first and second opposing ends;

b) the handle including a symmetrical mid-line and tapered portions extending from the mid-line, the handle including raised dimples arranged in a patten along its exterior;

c) the first opposing end including a spoon sized to remove a large volume of uncured cement in one sculpting motion and having sides of a thickness sufficient to remove uncured cement without bending;

d) the second opposing end including a spoon sized to remove a small volume of uncured cement from narrow joint spaces and having sides of a thickness sufficient to remove uncured cement without bending, the spoon being disposed at a reverse-angle relative to the first opposing end;

and

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e) the handle further including an integral raised ridge placed between the handle and each spoon.

Brief Description of the Drawings

5 In order to acquire a better understanding of the invention, reference may be had to the detailed description of the exemplary embodiments, set forth below, considered in conjunction with the appended drawings, in which:

10 FIGURE 1 is a side plan view of a surgical instrument of the present invention;

FIGURE 2 is a cross-sectional view looking along sight line 2-2 of Fig. 1;

15 FIGURE 3 is a top plan view of the surgical instrument of Fig. 1;

FIGURE 4 is a bottom plan view of the surgical instrument of Fig. 1;

20 FIGURE 5 is a side plan view of an alternate embodiment of the surgical instrument of the present invention;

FIGURE 6 is a top plan view of the surgical instrument of Fig. 5; and

FIGURE 7 is a bottom plan view of the surgical instrument of Fig. 5.

25 Detailed Description of Exemplary Embodiments

One type of instrument designed in accordance with the present invention is shown in Figs. 1-4, where a sculp generally designated by reference numeral 10 has an elongated handle 12 with two

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relatively flat opposing end sections 14 and 16. Each end section 14 and 16 includes a sculpting tool as described in greater detail below. The handle 12 is formed with a circular cross-section and tapers from a symmetrical mid-point 11 toward the opposing end sections 14 and 16. The handle 12 and the end sections 14 and 16 join at transition points 18a and 18b.

5 The symmetrical, tapered shape of the handle 12 improves the holding comfort of the instrument 10 during cement removal regardless of which end is used. Gripping means such as raised dimples 13 or other suitable irregular raised surface elements are formed in a pattern along the exterior of the handle 15 12 for allowing a surgeon to securely grip the surgical instrument 10 during the sculpting procedure.

The sculp 10 is formed of an injection molded, sterilizable, but non-autoclavable, plastic such as for example, cellulose acetate propionate, so the 20 sculp 10 can be discarded after use. An important feature of the invention is the design of the plastic sculpting instrument 10 which is of a relatively small profile for maximum visibility by the surgeon and which has the capability of reaching 25 tight and difficult-to-reach areas. The design also provides an instrument that is strong enough not to bend or break while the relatively thick, putty-like, uncured resin is being sculpted.

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As shown in Figs. 1-4, the sculp 10 is formed with a sculpting tool on the end sections 14 and 16. For example, a sculpting tool in the shape of a large spoon 20, is formed on the end 14 for the removal of a large quantity of cement. A sculpting tool in the shape of a small spoon 30 is formed on the end 16 for the removal of a smaller quantity of uncured cement in a more confined space.

As best shown in Figs. 1 and 3, the large spoon 20 is positioned at a reverse-angle relative to the small spoon 30 formed on the end 16 so that the spoons have an orientation that is more convenient to use. As shown in Fig. 1, the spoons 20 and 30 are formed at an angle relative to the long axis of the handle 12 to facilitate cement removal, preferably at an angle of about 30°.

The large spoon 20, at its widest part, is preferably 0.62" (1.58cm) wide and is about 1" (2.54cm) long. The sides 24 of the large spoon 20 are about 0.3" (0.76cm) thick at the deepest portion and about 0.01" (0.025cm) thick at the thinnest portion. The small spoon 30, at its widest part, is about 0.26" (0.66cm) wide and about 0.36" (0.91cm) long. The sides 34 of the small spoon 30 are about 0.14" (0.36cm) thick at the deepest part and about 0.12" (0.30cm) thick at the thinnest point. The sides 24 and 34, respectively, of spoons 20 and 30, should be thick enough or reinforced so that the spoons 20 and 30 do not bend during removal of the uncured cement.

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An integral structural reinforcing means such as a raised flange or ridge 19 is formed on the side of the end sections 14, 16, opposite the open surface of the spoons 20, 30. Fig. 2 illustrates the ridge 19 on the end section 14, which extends from the handle 10 and terminates at a point 22 on the spoon 20, as shown in Fig. 3, and at a point 33 on the spoon 30, as shown in Fig. 4. The strength of the surgical instrument 10 is substantially reinforced by the raised ridge 19 without sacrificing the surgeon's visibility or ability to sculpt uncured cement in hard-to-reach locations.

A second sculp formed in accordance with the present invention is shown in Figs. 5-7, where reference numeral 40 is used to identify the instrument. Sculp 40 includes the same features as the surgical instrument 10, except for the shape of the sculpting tools formed on the end sections 14 and 16. For example, a loop 50 is formed on the end section 14 for the removal of uncured cement in the narrow spaces of a cavity such as an intramedullary canal. The loop 50 includes an opening 52 that is useful for allowing surgeons to observe the amount of bone cement being removed. The loop 50 has a dimension of about 0.62" at its widest part and is about 1" (2.54cm) long. The sides 54 of the loop 50 are about 0.32" (0.81cm) thick which is sufficient to resist bending when bone cement is being removed.

A blade or knife 60 is formed on the end section 16 which is useful for removing uncured

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cement in crevices between the bone and the prosthesis. The blade or knife 60, as shown in Figs. 5-7, is formed on the end section 16 and positioned at a reverse-angle relative to the loop 50. The knife 60 is dimensioned at about 0.5" (1.27cm) at its widest point and tapers to a point 62. The knife 60 at its thickest portion is about 0.14" (0.36cm), and is about 1" (2.54cm) long. As illustrated in Fig. 5, the loop 50 and the knife 60 are formed at about a 30° angle relative to the long axis of the handle 12.

As with the surgical instrument 10, the surgical instrument 40 is formed with raised dimples 13 on the outer surface of the handle 12. The strength of the end sections 14, 16 is reinforced by the raised ridge 19 as in Figs. 1-4.

The present invention provides specifically designed disposable instruments for the removal of excess uncured cement, with each instrument incorporating a specific sculpting tool on its opposing ends. The dual application surgical instruments, with the reverse angle sculpting tools, provide the surgeon with the ability to use different tools on a single instrument, eliminating the need to change instruments as often during the cement removal process. The tapered handle design makes the instrument easier to hold and the raised dimple design reduces the tendency for the instrument to slip out of the surgeon's hand. The ends are strengthened by the raised ridge so that

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the instrument will not bend or break while sculpting the uncured cement and at the same time not impede the surgeon's visibility or ability to reach out-of-the-way locations.

5 It should be understood that the foregoing description is exemplary of the invention and not restricted, and that improvements and modifications can be made to the invention without departing from the spirit and scope of the invention as defined in
10 the appended claims.

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CLAIMS

What is claimed is:

- 1 1. A disposable surgical instrument for use
2 in removing uncured bone cement, comprising:
3 a) an elongated handle and opposing end
4 sections;
5 b) the handle including a middle portion
6 and tapered portions extending toward the opposing
7 end sections, the handle including external gripping
8 means;
9 c) each opposing end section including a
10 sculpting means having a shaped configuration for
11 sculpting uncured bone cement;
12 d) the end sections including an
13 integral structural reinforcing means extending
14 between the handle and the sculpting means; and
15 e) the handle and opposing end sections
16 being formed as a unitary structure of a
17 sterilizable molded plastic.

- 1 2. The surgical instrument of claim 1,
2 wherein the gripping means comprises raised dimples
3 arranged in a pattern along the exterior of the
4 handle.

- 1 3. The surgical instrument of claim 1 or
2 claim 2, wherein the sculpting means comprises a
3 loop having an opening in the center, the loop
4 having sides of a thickness sufficient to remove
5 uncured cement without bending.

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1 4. The surgical instrument of any preceding
2 claim, wherein the sculpting means comprises a knife
3 generally in the shape of an oval and tapering to a
4 point for the removal of uncured cement in crevices
5 between a bone and a prosthesis.

1 5. The surgical instrument of any preceding
2 claim, wherein the sculpting means comprises a spoon
3 having sides of a thickness sufficient to remove
4 uncured cement without bending.

1 6. The surgical instrument of any preceding
2 claim, wherein the structural reinforcing means
3 comprises a raised ridge for strengthening the end
4 sections.

1 7. The surgical instrument of any preceding
2 claim, wherein the sculpting means on the opposite
3 ends are disposed at reverse-angles relative to each
4 other.

1 8. The surgical instrument of any preceding
2 claim, wherein the handle includes a symmetrical
3 mid-line with the tapered portions extending on
4 opposite sides of the mid-line.

1 9. A surgical instrument for removing uncured
2 bone cement, comprising:

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- 3 a) an elongated handle formed of a
4 sterilizable plastic material having first and
5 second opposing ends;
6 b) the handle including a symmetrical
7 mid-line and tapered portions extending from the
8 mid-line, the handle including raised dimples
9 arranged in a pattern along its exterior;
10 c) the first opposing end including a
11 loop having an opening in the center for the removal
12 of uncured cement in narrow spaces of a cavity and
13 having sides of a thickness sufficient to remove
14 uncured cement without bending;
15 d) the second opposing end including a
16 knife generally in the shape of an oval and tapering
17 to a point for removing uncured cement between a
18 bone and a prosthesis, the blade being contiguous
19 with the handle and disposed at a reverse-angle
20 relative to the first opposing end; and
21 e) the handle further including an
22 integral raised ridge placed between the handle and
23 the loop and blade.

1 10. A surgical instrument for removing uncured
2 bone cement, comprising:

- 3 a) an elongated handle formed of a
4 sterilizable plastic material having first and
5 second opposing ends;
6 b) the handle including a symmetrical
7 mid-line and tapered portions extending from the

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8 mid-line, the handle including raised dimples
9 arranged in a pattern along its exterior;
10 c) the first opposing end including a
11 spoon sized to remove a large volume of uncured
12 cement in one sculpting motion and having sides of a
13 thickness sufficient to remove uncured cement
14 without bending;
15 d) the second opposing end including a
16 spoon sized to remove a small volume of uncured
17 cement from narrow joint spaces and having sides of
18 a thickness sufficient to remove uncured cement
19 without bending, the spoon being disposed at a
20 reverse-angle relative to the first opposing end;
21 and
22 e) the handle further including an
23 integral raised ridge placed between the handle and
24 each spoon.

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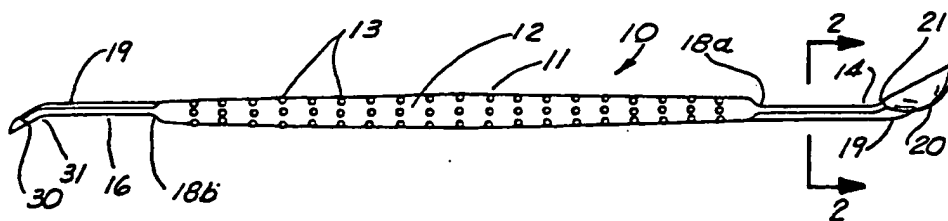


FIG. 1

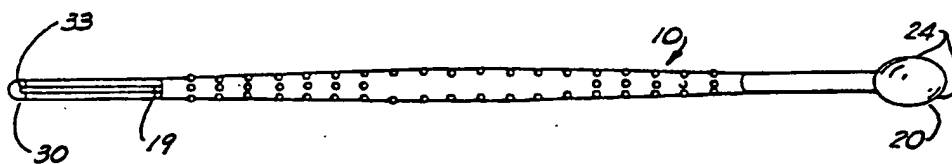


FIG. 3

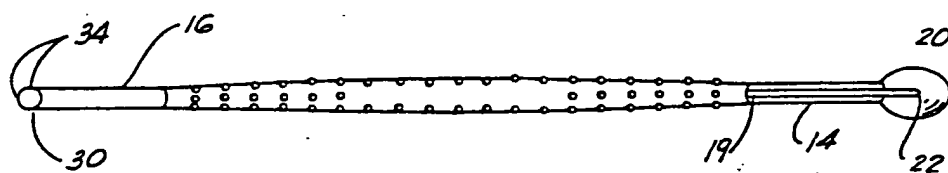


FIG. 4

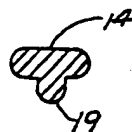


FIG. 2

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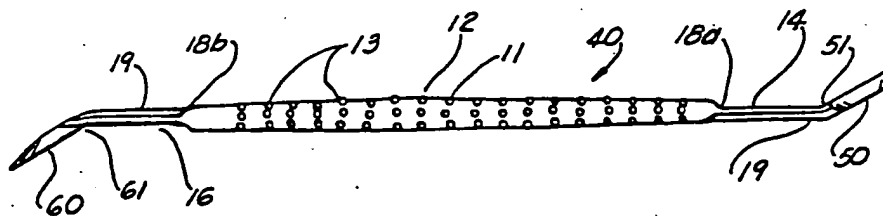


FIG. 5

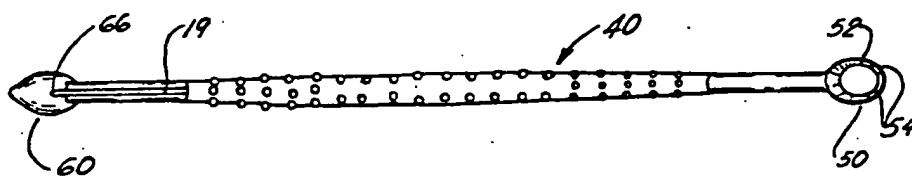


FIG. 6

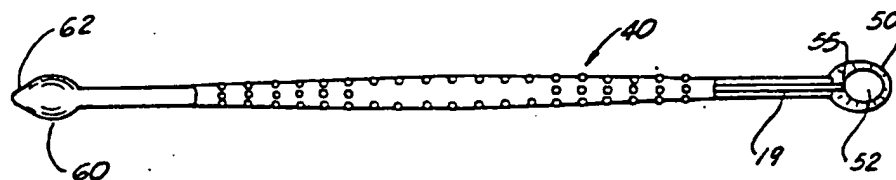


FIG. 7

INTERNATIONAL SEARCH REPORT

Int'l. application No.

PCT/US94/03531

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : A61B 17/00

US CL : 606/84, 93, 167

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/84, 86, 92, 93, 131, 159-162, 167

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	SU, A, 1438-743, (PENZA DOCTOR RETRAI), 23 November 1988. See all figures.	1-10
Y	US, A, 1,965,861. (R. S. SCHNEIDER), 10 July 1934. See page 1, lines 95-98.	2
Y	SMITH & NEPHEW RICHARDS ANNUAL PRODUCT CATALOG 1990, CMW CEMENT GUN SYSTEM BONE CEMENT ACCESSORY SYSTEM, page F-6.	3-5, 9, 10
Y	US, A, 2,543,999, (J. A. VOSS), 06 March 1951. See column 4, lines 49-60.	6, 9, 10



Further documents are listed in the continuation of Box C.



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